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COTTON, ABIGAIL MANDA	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,128	GRUBER, PETER	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *21 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/242,167.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/12/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20 and 22-23, drawn to a pharmaceutical composition for oral administration, comprising coated particles having a core containing an active ingredient, and a coating with at least one hydratable layer, classified in class 424, subclasses 439 and 489-502, for example.

II. Claim 21, drawn to a process for producing a pharmaceutical composition comprising an active ingredient coated with at least one layer containing a hydratable polymer, classified in class 439 and 489-502, for example.

III. Claim 24, drawn to a method for treating or preventing diseases by oral administration of the pharmaceutical composition including optionally adding 30 to 300% by weight of water and directly administering the composition to the mouth, classified in class 439 and 489-502, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make a materially different product, such as a product suitable for otic, ophthalmic or topical use, rather than an oral administration product.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups I and II may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Group II, the Examiner will be focusing on the patentability of the process itself, and not the composition of Group I. Conversely, in searching Group I, the Examiner will be focusing on the patentability of the composition and not the process itself. Accordingly, a search for both groups would pose an undue burden on the Office.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product can be used in a materially different process, such as in a process in which an amount of water other than the 30to 300% is added, or a method in which an aqueous solution

containing water and other oral administration ingredients, such as sweeteners or thickeners, is added.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups I and III may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Group I, the Examiner will be focusing on the patentability of the product itself, and not the process of using of Group III. Conversely, in searching Group III, the Examiner will be focusing on the patentability of the process and not the product itself. Accordingly, a search for both groups would pose an undue burden on the Office.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because Group III is directed to utilizing the composition to treat or prevent diseases, whereas Group II is directed to a method of preparing the composition. Thus, the methods have different functions and effects. The inventions are also not disclosed as capable of use together, because the steps involved in the process of making and the process of using the composition are temporally separated. That is, the steps of using the composition for treating or

preventing disease are not taught has being equivalent to, or useful as, steps performed for the purpose of preparing the composition, and vice versa.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups II and III may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Group III, the Examiner will be focusing on the patentability of the process of utilizing itself, and not the process of preparing of Group II. Conversely, in searching Group II, the Examiner will be focusing on the patentability of the process of preparing and not the process of utilizing the composition. Accordingly, a search for both groups would pose an undue burden on the Office.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Xavier Pillai on December 22, 2006, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-20 and 22-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21 and 24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

DETAILED ACTION

Claims 1-24 are pending in the application, with claims 21 and 24 having been withdrawn as drawn to non-elected inventions. Accordingly, claims 1-20 and 23 are being examined on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 6-9, 16-20 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,882,169 to Kimon Ventouras, issued November 21, 1989, in view of U.S. Patent No. 5,167,965 to Gary J. Schulz, issued December 1, 1992.

Ventouras teaches a pharmaceutical composition for oral administration comprising pellets containing a core with microparticles of at least one pharmaceutically active substance, an optional coating layer, and a swellable outer layer (see abstract, in particular.) Thus, it is considered that Ventouras teaches the composition comprising

the coated particles with a core containing the pharmaceutically active ingredients and a coating consisting of one or more layers, as recited in claim 1. Ventouras further teaches that when in contact with water, the outer layer of the pellet swells and rapidly becomes jellified, allowing the composition to be swallowed easily by any person who is in need of the pharmaceutically active substance (see column 1, lines 4-20, in particular.) Ventouras teaches that the swellable outer layer can contain swellable materials such as xanthan gum, sodium caboxymethylcellulose, alginates, and others (see column 3, lines 25-45, in particular), and thus teaches the hydratable polymers as recited in claims 1 and 3.

Ventouras does not specifically teach that the outer layer contains a salivation-promoting agent, as recited in claim 1, although Ventouras does teach that the pellets can contain additional flavourings and sweeteners, preferably in the swellable outer layer (see column 3, lines 57-60, in particular.)

Schulz teaches palatable granules for oral administration (see abstract and column 1, lines 5-55, in particular.) Schulz teaches that it is known to provide flavorings and sweeteners in such oral administration compositions, such as the well known sweeteners sucrose and fructose (salivation-promoting agent), and also teaches that citric acid (salivation-promoting agent) is commonly employed in combination with fruit flavorings in such compositions (see column 5, lines 13-25, in particular.) Accordingly,

Schulz teaches that is known in the art to provide sucrose and fructose as sweeteners, and/or citric acid as a flavoring component, in orally administered compositions.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the sweeteners and/or citric acid of Schulz in the swellable outer layer of Ventouras, because Ventouras teaches that the oral composition contains a swellable outer layer that can contain sweeteners and/or flavorings, and Schulz teaches that fructose, sucrose and citric acid are known in the art as sweeteners/flavorings that are suitable for oral pharmaceutical administration. Thus, one of ordinary skill in the art would have been motivated to provide citric acid, sucrose and/or fructose in the swellable outer layer of Ventouras, with the expectation of providing a suitable sweetener and/or flavorant for the orally administrable composition.

Regarding the "effective amount" of the salivation-promoting agent as recited in claim 1, it is noted that Ventouras et al. and Schulz render obvious providing the agents in order to sweeten or otherwise flavor the composition, as discussed above. Thus, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the sweetener and/or citric acid provided in the composition, according to the guidance provided by Ventouras and Schulz, to provide a composition having desired properties, such as desired taste and/or sweetness. It is noted that "[W]here the general conditions of a claim are

disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding the recitation that the coating layer or layers contains at least one hydratable polymer which "on contact with saliva or water, forms a coherent, mouldable, viscous, mass which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the mass, and release of active ingredient in the mouth," it is noted that, as discussed above, Ventouras teaches that the outer layer of the pellet becomes jellified on contact with water to allow if to be swallowed easily, and also teaches that the outer layer can comprise the same materials such as the hydratable polymer as claimed. Ventouras also teaches that the composition can form a viscous homogeneous suspension, like jam or jelly (see column 4, lines 13-16, in particular), and thus teaches that the composition can form a coherent, mouldable, viscous mass. It is furthermore considered that as the combined teachings of Ventouras and Shulz renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely slipperyness, lack of adherence to oral mucosa, prevention of active ingredient particle escaping an release in the mouth, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655,

1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Accordingly, claim 1 is considered to be obvious over Ventouras and Schulz.

Regarding claim 3, Ventouras teaches that the swellable polymer can comprise polymers such as hydroxypropylmethyl cellulose, xanthan gum, and alginates, as recited in the claim (see column 3, lines 25-45, in particular.) Regarding claim 7, Ventouras teaches that the active ingredient can be cimetidine, ranitidine, and others (see column 62, line 35 through column 3, line 5, in particular), as recited in the claim.

Regarding the amount of the outer swelling layer as recited in claim 6, Ventouras provides an exemplary embodiment of a multi-layer swellable pellet formulation (see Example starting in column 4, in particular), with a specific amount of swellable polymer provided. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of swellable polymer layer provided in the composition, according to the guidance provided by Ventouras and Schulz, to provide a composition having desired properties, such as desired water swelling properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 8-9, Ventouras and Schulz render obvious providing fructose, sucrose and/or citric acid in the outer layer, and thus render obvious the salivation-promoting agents as recited in the claims. Regarding claims 16 and 18, Ventouras teaches that the microparticles used for the invention can comprise a size of from 0.2-3.0 mm (see column 2, lines 29-35, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the size of the particle provided in the composition, according to the guidance provided by Ventouras and Schulz, to provide a composition having desired properties, such as desired administration properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 17, Ventouras teaches that the composition contains several of the particles, which form a perfectly homogeneous dispersion when put into water or saliva, and in which no individual grains can be perceived any more (see column 2, lines 10-20, in particular) and also teaches that the composition swells and becomes jellified upon contact with water (see column 1, lines 10-20, in particular.) Accordingly, it

is considered that Ventouras teaches a mouldable mass that forms on contact with saliva that cause the particles to stick together, as recited in the claim.

Regarding claim 19, Ventouras teaches that the composition can be packaged in a sachet for reconstitution with water (see paragraph bridging columns 3-4, in particular) and thus teaches an "anhydrous" composition, as recited in the claims. Regarding claim 20, Ventouras teaches that the composition can be put into water, such as in a cup of water, and then administered by spoon (see column 4, lines 10-16, in particular), and thus teaches that the mass is single, coherent, and viscous with a sufficient consistency to allow it to be taken without disintegrating by hand or spoon, as recited in the claim. Regarding the specific amount of water added, it is noted that Ventouras teaches that the composition is dispersed in water to provide a viscous preparation (see column 4, lines 4-10, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of water provided to form the viscous composition, according to the guidance provided by Ventouras, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 22, it is noted that Ventouras and Schulz teach the pharmaceutical composition containing the particles with pharmaceutical active ingredient, and a coherent viscous mass formed by contact with saliva, etc, and that coats (envelops) the particle, the composition also containing a salivation-promoting agent, and a hydratable polymer, as has been discussed for claim 1 above. Regarding the recitation of a polymer in "partly hydrated form" as recited in claim 22, it is considered that the swellable polymer of Ventouras is "at least partially hydrated" when placed in a cup with water or when contacted with saliva, as taught by Ventouras, and thus the composition is considered to be rendered obvious by the references.

Regarding claim 23, it is noted that Ventouras teaches that the formulation can be in the form of a dry suspension packed into sachets for reconstitution with water, and thus teaches a product pack as recited in the claim. The Examiner further notes that instructions for reconstituting such dry forms are well known in the art. Regarding the specific amount of water added, it is noted that Ventouras teaches that the composition is dispersed in water to provide a viscous preparation (see column 4, lines 4-10, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of water provided to form the viscous composition, according to the guidance provided by Ventouras, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 1-4, 6-12, 14-20 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,288,500 to Lars S. Ibsen, issued February 22, 1994.

Ibsen teaches an oral composition adapted to be dispersed in an aqueous carrier prior to administration, which comprises a multiplicity of particles comprising an active substance, that are combined with gelling or swelling agents that form a viscous medium around the particles and provides a masking surface layer to facilitate ingestion of the composition (see abstract and column 2, lines 5-35, in particular.) Ibsen teaches that the particles can be coated with at least one layer comprising the gelling or swelling agent (see column 6, lines 9-15, in particular), and thus is considered to teach coated particles with the coating consisting of one or more layers, as recited in claim 1. Ibsen teaches that the gelling or swelling agents can comprise polymers such as xanthan gum, polyvinylpyrrolidone, hydroxypropyl methylcellulose, and others (see column 5, lines 9-45, in particular), and thus teaches the coating containing the hydratable polymer as recited in claims 1 and 3.

Ibsen further teaches that the coating comprising the gelling or swelling agents can further comprise a weak acid to regulate the viscosity of the resulting substance

(see paragraph bridging columns 9-10, in particular.) Ibsen teaches that suitable weak acids can include tartaric acid, citric acid and others (see column 10, lines 10-12, in particular), and thus teaches providing salivation-promoting agents, as recited in the claim.

Ibsen does not teach a specific embodiment of a particle composition containing the coated core with the hydratable polymer and the specific acid that is tartaric acid or citric acid (salivation-promoting agent), as recited in claim 1. However, as Ibsen teaches that the acids are examples of suitable weak acids that could be incorporated into the coating of the composition, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide a composition having the tartaric or citric acid, with the expectation of providing a composition having a viscosity suitable for beneficial oral administration.

Regarding the "effective amount" of the salivation-promoting agent as recited in claim 1, it is noted that Ibsen teaches the weak acid is provided in an amount that gives a desired viscosity (see paragraph bridging columns 9-10, in particular.) Thus, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the weak acid provided in the composition, according to the guidance provided by Ibsen, to provide a composition having desired properties, such as desired viscosity. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover

the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding the recitation that the coating layer or layers contains at least one hydratable polymer which "on contact with saliva or water, forms a coherent, mouldable, viscous, mass which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the mass, and release of active ingredient in the mouth," it is noted that Ibsen teaches that the composition serves to mask uneven surfaces on the particles and prevents them from adhering to oral mucosa (see column 3, lines 30-45, in particular.) Ibsen also teaches that the gelling or swelling agents that form a viscous medium around the particles and provides a masking surface layer to facilitate ingestion of the composition (see abstract and column 2, lines 5-35, in particular), and thus teaches that the composition can form a coherent, mouldable, viscous mass, and Ibsen also teaches that the gelling or swelling agents can comprise the same polymers as the hydratable polymers as claimed. It is furthermore considered that as the combined teachings of Ibsen render the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely slipperyness, lack of adherence to oral mucosa, prevention of active ingredient particle escaping an release in the mouth, etc are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d

705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Accordingly, claim 1 is considered to be obvious over Ibsen.

Regarding the polymers having the specific viscosities as recited in claims 2 and 4, it is noted that Ibsen teaches that the gelling or swelling polymers can comprise such polymers as xanthan gum (nonionic polymer) and sodium carboxymethylcellulose (ionic polymer) (see column 5, lines 9-20, in particular.) Ibsen teaches that the gelling or swelling agent and concentration of the agent are selected to provide the desired viscosity, such as by selecting agent with a specific degree of polymerization or by mixing high viscous and lower viscous gelling agents (see column 4, lines 45-55, in particular), and the viscosity can be further optimized by regulating the chemical equilibria of reactants about the active substance (see column 5, lines 25-45, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the particular swelling or gelling polymer provided in the composition, and thus vary and/or optimize the viscosity of the polymer, according to the guidance provided by Ibsen, to provide an oral administration formulation having a desired viscosity. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 3, Ibsen teaches providing the hydratable polymers such as xanthan gum, sodium alginate, polyvinylpyrrolidone, etc (see column 5, lines 9-40, in particular), as recited in the claim.

Regarding claim 6, Ibsen teaches that the gelling or swelling agent can comprise from 0.05% to 20% of the composition (see column 5, lines 40-44, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of swelling and/or gelling agent provided as a coating in the composition, according to the guidance provided by Ibsen, to provide a composition having desired properties, such as desired water gelling and/or swelling properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 7, Ibsen teaches that the active substance can comprise cimetidine, naproxen, and others (see column 6, lines 40-66, in particular), as recited in the claim. Regarding claims 8-9, Ibsen teaches providing citric acid and/or tartaric acid

in the coating and thus teaches providing the salivation-promotion agents as recited in the claims.

Regarding claim 19, Ibsen teaches that the active ingredient particles can be coated with a coating composed of *at least one* layer comprising the gelling or swelling agent. Accordingly, it is considered that one of ordinary skill in the art would have found it obvious, based on the teachings of Ibsen, to provide two layers having gelling or swelling layers, because Ibsen teaches that *at least one layer* can be provided, thereby implying that two or more could also advantageously provided with the expectation of providing a formulation with improved for oral administration. Regarding the specific viscosity of the layers, as recited in claims 10-12, teaches that the gelling or swelling agent and concentration of the agent are selected to provide the desired viscosity, and the viscosity can be further optimized by regulating the chemical equilibria of reactants about the active substance (see column 5, lines 25-45, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the particular swelling or gelling polymer provided in the composition, and thus vary and/or optimize the viscosity of the polymer, according to the guidance provided by Ibsen, to provide an oral administration formulation having a desired viscosity. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding the specific types of polymers provided, as recited in claims 10-12, Ibsen teaches that the gelling or swelling polymers can include xanthan gum and hydroxypropyl methylcellulose (nonionic polymers) as well as sodium carboxymethylcellulose (ionic polymers) (see column 5, lines 9-20, in particular), and thus teaches the nonionic and ionic polymers as recited in claim 11. Ibsen also teaches that the polymers can be polyvinylpyrrolidone, sodium carboxymethylcellulose, polyacrylic acid or celluloses, as recited in claim 12 (see column 5, lines 9-20, in particular.)

Regarding the percent by weight of each layer as recited in claim 14, it is noted, as discussed above, that Ibsen renders a composition with two layers of gelling or swelling agent, and teaches that the type and amount of gelling agent is selected in relation to a desired viscosity, as has also been discussed above. Ibsen further teaches that an amount of the gelling agent provided in the composition can be from 0.05 to 20% by weight, which is a range that encompasses the ranges recited in claim 14. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the layers provided in the composition, according to the guidance provided by Ibsen, to provide a composition having desired properties, such as a desired viscosity upon contacting water. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 15, Ibsen teaches that the particles can further comprise a controlled-release coating to prolong the effect of the active ingredient and/or to mask the taste of the active (see column 6, lines 15-30, in particular), and thus teaches providing a taste-masking coating that delays the release of the active ingredient, as recited in the claim.

Regarding claims 16 and 18, Ibsen teaches that the particles typically have a size in the range of from 0.05 to 7 mm (see column 6, lines 30-40, in particular), which is a range that encompasses those claimed, and teaches that the size is selected for easier swallowing. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the size of the particles provided in the composition, according to the guidance provided by Ibsen, to provide a composition having desired properties, such as desired ease of administration. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 17, Ibsen teaches that the gelling agent forms a highly viscous medium (gel) around the particles upon contact with water (e.g. saliva) (see column 6,

lines 8-15, in particular.) Ibsen also teaches that the viscosity of the composition can be varied according to the selection of the gelling or swelling agent, concentration, and other factors, as has been discussed above. Thus, it is considered that Ibsen teaches a composition with coated particles that form a mouldable mass upon contact with saliva that causes the particles to stick together, as recited in the claim. It is furthermore noted that as the teachings of Ibsen renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely moldability on contact with saliva and particles that stick together, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding claim 19, Ibsen teaches that the particles of the composition can be provided in dry form prior to use (see column 10, lines 45-60, in particular), and thus teaches a composition that is essentially anhydrous prior. Regarding claim 20, Ibsen teaches that the composition can also be provided in the form of a pre-gelled dispersion having the carrier mixed therein (see column 10, lines 45-60, in particular.) Regarding the specific amount of the water provided, and the viscosity of the resulting mass, Ibsen teaches that the dosage can be mixed with an aqueous carrier and other viscosity

affecting substances in amounts selected to achieve a satisfactory viscosity (see column 10, lines 25-45, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of carrier and/or viscosity affecting components provided in the composition, according to the guidance provided by Ibsen, to provide a composition having desired properties, such as a desired viscosity and desired ease of administration. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 22, it is noted that Ibsen teaches the pharmaceutical composition containing the particles with pharmaceutical active ingredient, and a coherent viscous mass formed by contact with an aqueous carrier, and that coats (envelops) the particle, the composition also containing a salivation-promoting agent, and a hydratable polymer, as has been discussed for claim 1 above. Regarding the recitation of a polymer in "partly hydrated form" as recited in claim 22, it is considered that the gelling or swelling polymer of Ibsen is "at least partially hydrated" when contacted with an aqueous carrier, as taught by Ibsen, and thus the composition is considered to be rendered obvious by the references.

Regarding claim 23, Ibsen teaches that the composition can be provided in a dry form, such as in a sachet that is mixed with an aqueous carrier (see column 10, lines

45-65, in particular), and thus teaches the product pack as recited in claim 23. The Examiner further notes that instructions for reconstituting such dry forms are well known in the art. Regarding the amount of water to add to the dry form, it is noted that Ibsen teaches that the dosage can be mixed with an aqueous carrier in an amount selected to achieve a satisfactory viscosity (see column 10, lines 25-45, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of aqueous carrier provided in the composition, according to the guidance provided by Ibsen, to provide a composition having desired properties, such as a desired viscosity and ease of administration. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,288,500 to Lars S. Ibsen, issued February 22, 1994, as applied to claims 1-4, 6-12, 14-20 and 22-23 above, and further in view of U.S. Patent No. 5,476,668 to Kobayashi et al, issued December 19, 1995.

Ibsen is applied as discussed above, and teaches particles coated with a gelling or swelling polymer, such as hydroxypropyl methyl cellulose, where the coated particles form a high viscosity medium in contact with an aqueous carrier. Ibsen also teaches that the viscosity of the composition can be selected by choosing a polymer with a

specific degree of polymerization (see column 4, lines 44-56, in particular.) Ibsen also renders obvious a composition containing two layers with the gelling or swelling polymers.

Ibsen does not specifically teach that the polymers have an average particle size not exceeding 200 microns, as recite in claim 5, or wherein the outermost layer has a polymer particle size not exceeding 50 microns, as recited in claim 13.

Kobayashi et al. teaches that cellulose ethers (e.g. hydroxypropyl methyl cellulose) are known to be used for film coating of pharmaceutical preparations (see column 1, lines 15-40, in particular.) Kobayashi et al. teaches that the cellulose ethers can be obtained having a high degree of polymerization, and thus a higher viscosity, than other low degree polymerization forms (see column 1, lines 15-40, in particular.) Kobayashi et al. teaches that the cellulose ethers with the high degree of polymerization can be pulverized to an average particle size on the order of 50 microns, which meets the range limitations as recited in claims 5 and 13.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the cellulose ether particles having a high degree of polymerization as taught by Kobayashi et al. in the coated particle composition of Ibsen, because Ibsen teaches that the coating can comprise polymers such as cellulose ethers, including hydroxypropyl methyl cellulose, and that

such polymers can be selected in relation to their degree of polymerization to provide a desired viscosity, whereas Kobayashi et al. teaches a particulate form of cellulose ether particles having a high degree of polymerization and thus a high viscosity. Thus, one of ordinary skill in the art would have been motivated to provide the cellulose ether particles with the high degree of polymerization in the coated particle composition of Ibsen, with the expectation of providing a suitable gelling or swelling polymer capable of providing a viscous medium about the particles upon contact with water.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-12, 14-19 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,709,678 to Peter Gruber, issued March 23, 2004. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are to a pharmaceutical composition that is coherent, moldable, viscous, slippery on the surface and does not adhere to oral mucosa, the composition having particles comprising an active ingredient selected from a specific group, a coating about the particle, the coating comprising a specific hydratable polymer, and a salivation-promoting agent, whereas the instant claims are drawn to the oral pharmaceutical composition containing particles with an active ingredient, the particles being coated with a hydratable layer, and a salivation-promoting layer. Thus, the instant claims are obvious over the patented claims that recited specific active agents and hydratable polymers, and thus instant claims 1-4, 6-12, 14-19 and 22 are not patentably distinct over claims 1-12 of the Gruber patent.

Conclusion

No claims are allowed

The prior art made of record and not relied upon that is considered pertinent to applicant's disclosure is listed in the accompanying PTO-892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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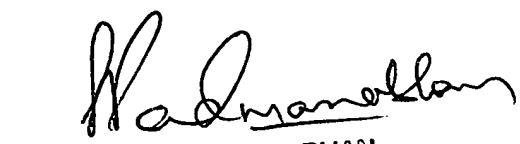

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